

REMARKS

This Supplemental Response is provided in response to Office Action dated April 07, 2004 and the Advisory Action mailed April 20, 2004, which indicated that the Amendments filed April 07, 2004 were entered but did not place the application in condition for allowance. Reconsideration of the present application in light of the following amendments and remarks is respectfully requested. Claims 1-8 and 10-16 are currently pending and under consideration. Claim 1 is currently amended to more specifically recite certain aspects of the claimed invention, including those previously recited in claim 8, which is canceled. Accordingly, support for the instant amendment is clearly provided in the specification and claims as originally filed and do not constitute new matter. Furthermore, specific support for the conditional marker being a red-ox dye is provided, *e.g.*, on page 9, line 3. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Claim Objections

Applicant thanks the Examiner for her withdrawal of the objection to claim 4, in light of the Amendment filed April 07, 2004.

Rejection under 35 U.S.C. § 102(b)

Claims 1-6 and 8-15 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Townsend *et al.* (WO 96/40980). In particular, the Action mailed January 07, 2004 alleges that the cited reference teaches a composition comprising substrates and detectable markers, including those of the presently claimed invention.

In the Amendment filed April 04, 2004, Applicant amended the claims to specifically recite the feature that the conditionally detectable marker is a vital dye. In response to this Amendment, the Examiner indicated that Applicant's arguments were directed to methods of the invention, rather than the claimed compositions. Furthermore, the Examiner maintained

the view that the previously cited references taught and suggested the claimed composition. Applicant respectfully submits that the remarks in the Amendment filed April 04, 2004 were directed to the novelty and non-obviousness of the claimed compositions and that discussion of the related methods was provided to place the claimed invention in the appropriate context. Applicant regrets any confusion this may have caused and respectfully requests that the Examiner reconsider the claims in light of the amendments and remarks provided in the previous Amendment and this Supplemental Response.

Regarding the maintained rejection under 35 U.S.C. § 102(b), Applicant traverses this ground for rejection and submits that each and every element of the claims of the present invention is not present in the cited reference. Applicant notes that for a prior art reference to anticipate a claim, it must disclose each feature of the claimed invention. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicant submits that the cited reference fails to teach a composition comprising a substrate for an enzyme that is substantially absent from a target organism, as presently claimed. Rather, the composition described by Townsend *et al.* includes substrates for enzymes that are present in target organisms. Accordingly, Applicant submits that the cited reference fails to teach or suggest each element of the presently claimed invention and, therefore, does not anticipate the claimed invention. Applicant respectfully requests that this rejection be withdrawn.

Nonetheless, without acquiescence to this basis of rejection and solely to expedite prosecution of the instant application, Applicant have amended claim 1 to specifically recite that the conditionally detectable marker is a red-ox dye. Support for this amendment is provided, *e.g.*, on page 9, line 3, of the instant application. Applicant submits that Townsend *et al.* fails to teach a composition comprising a red-ox dye. Rather, Townsend *et al.* is directed to a bacterial growth medium containing two or more different enzyme substrates, each hydrolyzed by a different bacterial enzyme to cause or produce a detectable signal. Since red-ox dyes are not enzyme substrates, Townsend *et al.* fails to teach this element of the claimed composition and, therefore, fails to anticipate the claimed composition, which comprises a red-ox dye in addition to an enzyme substrate.

Furthermore, Applicant submits that the skilled artisan would appreciate that the presently claimed compositions are very different than the compositions described in Townsend *et al.* Although the Examiner asserts that the Abstract of Townsend *et al.* teaches a composition comprising substrates and detectable markers, a careful reading of Townsend *et al.*, including the Abstract, clearly indicates that the only detectable markers contemplated by Townsend *et al.* are enzyme substrates, which produce a detectable signal when hydrolyzed by a bacterial enzyme to release a detectable moiety. Furthermore, Applicant submit that the Examiner's assertion that the compositions taught by Townsend *et al.* contemplate the use of tetrazolium is an inaccurate interpretation of the teachings of Townsend *et al.* Applicant point out that Townsend *et al.* mentions the use of tetrazolium in the Background of the Invention, when providing examples of inferior methods of attempting to determine bacterial concentration in food. Nowhere does Townsend *et al.* describe compositions containing tetrazolium in combination with a substrate for a bacterial enzyme or methods of detecting bacteria by using both tetrazolium (or any other red-ox dye) and a substrate for a bacterial enzyme. Accordingly, Applicant submit that Townsend *et al.* fails to teach a composition that falls within the scope of the instant claims and, thus, fails to anticipate the present invention.

In light of the claim amendments and comments provided above, Applicant respectfully request that the Examiner reconsider and withdraw this basis of rejection.

Rejections under 35 U.S.C. 103(a)

Claims 1-8 and 10-15 remain rejected as allegedly being obvious in light of Townsend *et al.* In particular, the Action mailed January 07, 2004 alleges that Townsend *et al.* teaches a composition for detecting viable bacteria, yeast, or fungi in a test sample by using detectable markers. The Action concedes that Townsend *et al.* does not specifically teach the composition comprising tetrazolium red, but alleges that one of skill in the art would have found it obvious in light of the teachings of Townsend *et al.* for the skilled artisan to use tetrazolium red in the composition of Townsend *et al.* with a reasonable expectation for successfully detecting microorganisms.

Applicant respectfully traverses this ground for rejection and submits that one of skill in the art would not view the presently claimed invention as obvious in light of Townsend *et al.* Indeed, the Examiner has failed to establish a *prima facie* case of obviousness, since the Action fails to establish that each element of the presently claimed invention is taught or suggested by Townsend *et al.* Specifically, Townsend *et al.* does not teach or suggest a detectable substrate for an enzyme that is substantially absent from a target organism. Rather, Townsend *et al.* teaches a bacterial growth medium comprising three or more enzyme substrates, which are acted upon by an enzyme present in a target organism.

Furthermore, regarding tetrazolium red, Townsend *et al.* state in the Background of the Invention that previous attempts to measure bacterial concentration have included indicators that change color in the presence of a microorganism, but effectively dismiss the use of such dyes in their described composition, since they do not serve as a source of a required nutrient (page 2, lines 23-27). Thus, Townsend *et al.* actually teach away from the use of a red-ox dye, as presently claimed, in a composition further comprising a substrate for an aminopeptidase. Accordingly, the skilled artisan would not be motivated to include a red-ox dye, which is not a target for a bacterial enzyme and does not comprise a nutrient moiety, in the composition described by Townsend *et al.* to achieve the claimed invention. Therefore, Townsend *et al.* fail to teach this element of the claimed composition, and Applicant respectfully requests that this rejection be withdrawn.

Claims 1-8 and 10-16 remain rejected under 35 U.S.C. § 103(a) as allegedly being obvious in light of Townsend in view of Stern *et al.* (US Patent No. 5,891,709). The Action of January 07, 2004 alleges that Townsend *et al.* teaches a composition for detecting viable bacteria, yeast, or fungi in a test sample by using detectable markers, and Stern *et al.* disclose using antibiotics to select for particular bacterial strains. The Action concedes that Townsend *et al.* does not specifically teach using tetrazolium red as a detectable marker or antibiotics as selection for particular bacterial strains.

Applicant respectfully traverses this ground for rejection and submits that one of skill in the art would not find the presently claimed invention obvious in view of Townsend *et al.* and Stern *et al.*, either alone or in combination. As noted above, Townsend *et al.* fails to teach a composition comprising a substrate for an enzyme absent in the target microorganism. Furthermore, Townsend *et al.* fail to teach a composition comprising a red-ox dye and, in fact teach away from the use of such non-substrate indicators, as noted above. Applicant submits that Stern *et al.* does not remedy the deficiencies of Townsend *et al.*, since Stern *et al.* also does not teach or suggest the use of a red-ox dye in combination with an enzyme for a substrate absent in a target organism. Accordingly, Applicant submits that Townsend *et al.*, even in light of Stern *et al.* clearly fails to teach each element of the claimed invention and, therefore, does not render the claimed invention obvious. Applicant respectfully requests that this rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicant respectfully submits that the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Should any remaining issues exist, the Examiner is urged to contact the undersigned attorney at (206) 622-4900.

Respectfully submitted,
SEED Intellectual Property Law Group PLLC



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Enclosures:

Request for Continued Examination (RCE)
Extension of Time Petition (+copy)

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